## REMARKS

Claims 23-31, as amended, and new claims 32-34 are pending in this application for the Examiner's review and consideration. Claims 1-22 were canceled without prejudice as a result of a restriction requirement. Applicant reserves the right to file one or more divisional or continuation applications to pursue the subject matter of canceled claims 1-22 or any other unclaimed subject matter. Independent method claim 23 was amended, to recite that the composition comprises an exfoliant, a hydrophobic moisturizing agent, and a hydrophilic moisturizing agent in addition to the hydrogen peroxide and the antimicrobial agent and/or anti-inflammatory agent. Claims 25 and 27-28 were similarly amended. New claims 32-34 simply recite each dermatological condition included in claim 23. No new matter is added by these claim amendments so that their entry at this time is warranted.

## THE CLAIMS

The present invention is directed to a method of treating, preventing, or managing a dermatological condition selected from the group consisting of a scalp condition, a hair condition, and a nail condition in a patient. The method involves administering to the patient a therapeutically effective amount of a composition comprising (1) hydrogen peroxide, (2) a hydrophilic moisturizing agent, (3) a hydrophobic moisturizing, (4) an exfoliant, and (5) one or more dermatological agents selected from an antimicrobial agent an anti-inflammatory agent, or a combination thereof. A method of treating, preventing, or managing a dermatological condition using a composition comprising an antimicrobial agent, an anti-inflammatory agent, or a mixture thereof and a combination of an exfoliant; a hydrophilic moisturizing agent, and a hydrophobic moisturizing agent and hydrogen peroxide, is not disclosed or suggested by any reference cited by the Examiner.

## THE REJECTION UNDER 35 U.S.C. § 102(B)

Claims 21-31 were rejected under 35 U.S.C. § 102(b) as being anticipated by international application no. PCT/US90/04649 published as WO 91/02538 ("the '538 application"), for the reasons set forth on pages 2-3 of the Office Action. The Office Action indicates that claims 21-31 are rejected. Claims 1-22, however, were withdrawn and subsequently canceled due to a restriction requirement. Accordingly, only claims 23-31 and new claims 32-34 are pending.

The '538 application discloses a composition comprising a film forming protein and a reducing agent and may optionally include a reactive zinc salt, a cationic polymer and a

cationic or nonionic surfactant. The compositions may further include oxidizing agents and/or antioxidants (*See, e.g.*, the '538 application, page 1, lines 1-7 and page 2, lines 26-32). The compositions are allegedly useful for treating a variety of conditions (*See, e.g.*, page 1, line 29 to page 2, line 10).

The '538 application does not anticipate claims 23-31. Independent claim 23, as amended, recites that the claimed composition comprises each of (1) hydrogen peroxide, (2) a hydrophilic moisturizing agent, (3) a hydrophobic moisturizing, (4) an exfoliant, and (5) one or more dermatological agents selected from an antimicrobial agent an anti-inflammatory agent, or a combination thereof. The '538 application does not disclose a composition that includes the combination of a hydrophilic moisturizing agent, a hydrophobic moisturizing, and an exfoliant, as presently claimed. Since anticipation requires that each and every element of a claim must be taught by a single prior art reference, the '538 application does not anticipate claims 23-31. For the above reasons, Applicant respectfully requests that the rejection of claims 23-31 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

The '538 application also does not render claims 23-31 obvious. As discussed above, the '538 application fails to disclose or suggest using a composition that includes an antimicrobial agent an anti-inflammatory agent, or a combination thereof; the combination of an exfoliant, a hydrophilic moisturizing agent, and a hydrophobic moisturizing agent; and hydrogen peroxide, as presently claimed. Specifically, the '538 application does not disclose or suggest the combination of an exfoliant, a hydrophilic moisturizer, and a hydrophobic moisturizer. The combination of the an exfoliant, a hydrophilic moisturizer, and a hydrophobic moisturizer, advantageously helps the antimicrobial agent an anti-inflammatory agent, or a combination thereof penetrate the skin and the combination is superior to any of these components individually. The exfoliant functions by removing the dead or dying skin cells, enabling the skin to better absorb moisture from the atmosphere (See e.g., Specification, page 12, lines 3-6), the hydrophobic agents prevent the loss of water from the skin (See e.g., Specification, page 12, lines 6-8), and the hydrophilic agents moisturize the skin by absorbing moisture or facilitating hydration of the skin (See e.g., Specification, page 12, lines 6-8). The '538 fails to disclose or suggest a dermatological composition that includes the combination of an exfoliant, a hydrophilic moisturizer, and a hydrophobic moisturizer, much less this combination further combined with hydrogen peroxide. The combination of an exfoliant, a hydrophilic moisturizer, and a hydrophobic moisturizer and hydrogen peroxide act in a synergistic manner to provide enhanced efficacy in treating dermatological conditions. The '538

application does not disclose or suggest a composition that includes an antimicrobial agent an anti-inflammatory agent, or a combination thereof in combination with an exfoliant, a hydrophilic moisturizer, and a hydrophobic moisturizer and hydrogen peroxide or the unexpected advantages of such a composition.. Accordingly, the '538 application does not even render claims 23-31 obvious.

## **CONCLUSION**

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

No fees are believed to be required for this submission. Should any fees be required, however, please charge those fees to Pennie & Edmonds llp deposit account no. 16-1150.

Respectfully submitted,

Date September 17, 2003

Paul E. Dietze

For: Victor N. Balancia

(Reg. No. 45,627)

(Reg. No. 31,231)

PENNIE & EDMONDS LLP

1667 K Street, N.W. - Suite 1000 Washington, DC 20006-4706

(202) 496-4400